

IN THE CLAIMS

Please amend the claims as follows:

Claims 1-20 (Cancelled).

Claim 21 (Currently Amended): A composition, comprising:

an extremely poorly water-soluble drug; and

a porous silica material;

wherein:

the composition is obtained by treating a mixture comprising the porous silica material and the extremely poorly water-soluble drug with a supercritical fluid or subcritical fluid of carbon dioxide;

the extremely poorly water-soluble drug has a solubility in water at 25 °C of less than 10 µg/mL prior to treatment; and

the porous silica material has an average pore diameter ~~in a range of~~ from 1 to 20 nm, a total pore volume of ~~where~~ pores having diameters within  $\pm 40\%$  of the average pore size ~~account~~ diameter accounts for at least 60% of a ~~total pore volume of~~ all pores of the porous silica material, and the porous silica material has an X-ray diffraction ~~spectrum~~ pattern including at least one peak at a position of a diffraction angle ( $2\theta$ ) corresponding to a  $d$  value of at least 1 nm.

Claim 22 (Previously Presented): The composition according to claim 21, wherein the porous silica material has a specific surface area of from 100 to 2,000 m<sup>2</sup>/g.

Claim 23 (Previously Presented): The composition according to claim 21, wherein a mixing ratio the porous silica material to the extremely poorly water-soluble drug is from 0.1:1 to 1,000:1.

Claim 24 (Previously Presented): The composition according to claim 21, wherein the extremely poorly water-soluble drug comprises 2-benzyl-5-(4-chlorophenyl)-6-[4-(methylthio)phenyl]-2H-pyridazin-3-one.

Claim 25 (Withdrawn – Currently Amended): A medicinal preparation comprising a the composition with an extremely poorly water-soluble drug contained therein as defined in according to claim 21.

Claim 26 (Withdrawn – Currently Amended): A process for producing a the composition with an extremely poorly water-soluble drug contained therein as defined in according to claim 21, the process comprising:

placing a porous silica material and ~~said an~~ extremely poorly water-soluble drug in a pressure-resistant vessel;

filling ~~said the~~ pressure-resistant vessel with carbon dioxide;

~~treating said porous silica material and said extremely poorly water-soluble drug while controlling maintaining the vessel at a temperature and pressure within said vessel such that the carbon dioxide is maintained in as a supercritical state fluid or a subcritical state fluid;~~  
and

discharging the carbon dioxide to recover the resulting composition;

wherein ~~said the~~ porous silica material has an average pore diameter ~~in a range of~~ from 1 to 20 nm, a total pore volume of pores having diameters within  $\pm 40\%$  of ~~said the~~

~~average pore size account~~ diameter accounts for at least 60% of a ~~total pore~~ volume of all pores of said the porous silica material, and ~~in the porous silica material has an~~ X-ray diffractometry, ~~said porous silica material has~~ diffraction pattern including at least one peak at a position of a diffraction angle ( $2\theta$ ) corresponding to a  $d$  value of at least 1 nm.

Claim 27 (Withdrawn – Currently Amended): The process of claim 26, wherein a weight ratio of ~~said the~~ extremely poorly water-soluble drug to ~~a the~~ supercritical fluid or subcritical fluid of carbon dioxide is from 1:1 to 1:1,000,000.

Claim 28 (Withdrawn – Currently Amended): The process of claim 26, wherein maintaining the vessel comprises maintaining the vessel at a temperature of treatment with a supercritical fluid or subcritical fluid is from – 40 to 100°C.

Claim 29 (Withdrawn – Currently Amended): The process of claim 26, wherein maintaining the vessel comprises maintaining the vessel at a pressure of treatment with a supercritical fluid or subcritical fluid is from 1 to 50 MPa.

Claim 30 (Withdrawn – Currently Amended): The process of claim 26, wherein the porous silica material and the extremely poorly water-soluble drug are maintained in contact with the a time of treatment with a supercritical fluid or subcritical fluid of carbon dioxide is for a period of from 1 minute to 24 hours.

Claim 31 (Withdrawn – Currently Amended): A process for producing a composition ~~with an extremely poorly water-soluble drug contained therein as defined in~~ according to claim 21, ~~the process comprising:~~

placing a porous silica material and ~~said-an~~ extremely poorly water-soluble drug in a pressure-resistant vessel;

~~maintaining controlling the vessel at a temperature within said vessel such that at~~  
~~which~~ carbon dioxide ~~will be maintained is~~ in a ~~the form of a~~ supercritical state-fluid or a subcritical statefluid;

~~-filling said pressure-the~~ vessel with carbon dioxide at ~~such-a~~ pressure such that carbon dioxide is ~~maintained in said-the form of a~~ supercritical state-fluid or a subcritical statefluid;

~~maintaining said-supercritical state or subcritical state to treat said~~ treating the  
~~peruous-porous~~ silica material and ~~said-the~~ extremely poorly water-soluble drug with the  
supercritical fluid or subcritical fluid of carbon dioxide; and

discharging carbon dioxide to recover the resulting composition;

wherein ~~said-the~~ porous silica material has an average pore diameter ~~in a range of~~  
from 1 to 20 nm, a total pore volume of pores having diameters within  $\pm 40\%$  of ~~said-the~~  
average pore size ~~account diameter accounts~~ for at least 60% of a ~~total-pore~~ volume of ~~said~~  
all pores of the porous silica material, and the porous silica material has an in-X-ray  
diffraction pattern including at least one peak  
at a position of a diffraction angle ( $2\theta$ ) corresponding to a  $d$  value of at least 1 nm.

Claim 32 (Withdrawn – Currently Amended): The process according to claim 31,  
wherein a weight ratio of ~~said-the~~ extremely poorly water-soluble drug to a ~~the~~ supercritical  
fluid or subcritical fluid of carbon dioxide is from 1:1 to 1:1,000,000.

Claim 33 (Withdrawn – Currently Amended): The process according to claim 31,  
wherein treating the porous silica material and the extremely poorly water-soluble drug

comprises treating at a temperature of treatment with a supercritical fluid or subcritical fluid  
~~is from~~ – 40 to 100°C.

Claim 34 (Withdrawn – Currently Amended): The process according to claim 31,  
wherein treating the porous silica material and the extremely poorly water-soluble drug  
comprises treating at a pressure of treatment with a supercritical fluid or subcritical fluid is  
from 1 to 50 MPa.

Claim 35 (Withdrawn – Currently Amended): The process according to claim 31,  
wherein treating the porous silica material and the extremely poorly water-soluble drug  
comprises treating for a period of a time of treatment with a supercritical fluid or subcritical  
~~fluid is from~~ 1 minute to 24 hours.